

NOV - 5 1999



K993394

August 30, 1999

Special 510(k) Summary

Echo-Scan 4.x

Easy-Scan 1.x

Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person

Florian Eisenberger
Director, Regulatory Affairs & Quality Assurance
Phone ++49-89-32175-830
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Common, Classification & Proprietary Names

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Proprietary Name:	Echo Scan Easy-Scan

Predicate Device

TomTec Echo-Scan K963807

Device Description

The TomTec acquisition software products Echo-Scan and Easy-Scan are combining 3D and 4D Acquisition Software and Echo-View™ / Easy-View Review Software for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing. It is the appropriate Software solution for TomTec's add-on accessories for existing ultrasound imaging systems, and is intended to control position and movement of ultrasound transducers for the acquisition of 2 dimensional image slices throughout a volume of interest. The 4D Echo-Scan™ Software acquires sets of 2D images and stores them digitally in a special 3D image file format for subsequent 3D tomographic reconstruction and surface rendering.

The 4D Echo-Scan™ is a software module for the high performance computer system Compact High or Professional based on Microsoft Windows NT™ 4.0 operating system standards.

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Intended Use

Echo-Scan™ is intended to acquire, store, retrieve and analyze digital ultrasound images and Color Doppler images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.

Echo-Scan™ can import certain digital 2D or 3D image file formats for 3D tomographic reconstructions and surface rendering. It is intended as a general purpose image acquisition and digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastro-enterology, urology, surgery, obstetrics and gynecology.

Technological Characteristics Comparison

The new Echo-Scan NT is a modified version of the filed Echo-Scan system, which has been transferred to Windows NT operating system standards.

The graphic user interface has been improved for faster and easier application. Easy-Scan is a clinical application oriented subset of the Echo-Scan Software, which makes handling easier and more efficient.

Test Discussion

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Florian Eisenberger
Manager Regulatory Affairs
TomTec Imaging Systems
Edisonstrasse 6
857176 Unterschleissheim,
Germany

Re: K993394
Echo Scan 4.x, Easy Scan 1.x
Dated: September 30, 1999
Received: October 8, 1999
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Eisenberger:

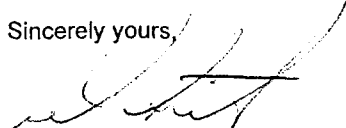
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993394

Device Name: TOMTEC Echo Scan

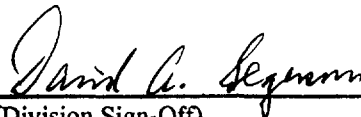
Indications For Use

Echo-Scan™ 4.1 is intended to acquire, store, retrieve and analyze digital ultrasound images for computerized 3-dimensional and 4-dimensional (dynamic 3D) image processing.

Echo-Scan™ 4.1 can import certain digital 2D or 3D image file formats for 3D tomographic reconstructions and surface rendering. It is intended as a general purpose image acquisition and digital 3D ultrasound image processing tool for cardiology, radiology, neurology, gastro-enterology, urology, surgery, obstetrics and gynecology.

(PLEASE DO NOT WRITE BELOW LINE LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993394

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐